

implant differs substantially from applicants' "substantially cylindrical body portion" as indeed it must in order to provide the required distraction action described at column 13, line 26 et seq. and illustrated in Figs. 11-13. While applicants' recitation "substantially cylindrical body portion" does allow for some limited deviation from a cylinder, it cannot be construed so as to dispense with a cylindrical configuration altogether or, as the Examiner would construe it, to be "unlimited" and therefore readable on any configuration including the non-cylindrical configuration of the Marino implant. Regarding the construction of claim terms such as "substantially", see *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 821-22, 6 USPQ2d 2010, 2012 (Fed. Cir. 1988); *Modine Manufacturing Co. v. International Trade Commission*, 75 F.3d 1545, 1554, 37 USPQ2d 1609, 1615 (Fed. Cir. 1996).

The anchoring fins of the Marino implant extend outwardly from the body of insert 20 but they cannot be said to extend *radially* outward as in applicants' claimed implant. As clearly illustrated in all of the embodiments of the Marino implant shown in the drawings, the anchoring fins are attached to that portion of insert 20 which does not possess a substantially cylindrical body portion and, therefore, does not possess a *radius*.

The Examiner asserts that applicants' claims recite an "intended use" and states that such "intended use" can be given no weight in the absence of any distinguishing structure. While it is correct to say that the recitation of a use, or utility, carries no patentable weight in and of itself (*Ex parte Mashan* cited by the Examiner and other decisions), applicants' claims do not recite an intended use. Applicants' claims do recite that each of the at least two tabs extending radially outward from the substantially cylindrical body possess a "configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within a vertebral body". This recitation is *not* a recitation of intended

use but clearly one of structure, specifically, the structure of the tabs. And the structure of applicants' tabs is such that they are adapted to be received within suitably configured recesses *previously formed* in the vertebral endplates as distinguished from the Marino et al. knife-like anchoring fins which are designed to *cut into* the vertebral endplates.

The Examiner at page 5 of the Office Action states that applicants rely on the *length* of the tabs as a patentably distinguishing feature of their invention not recited in the claims. This is not the case. Applicants do not maintain that their claims are patentable because the tabs are of sufficient length to engage or access cancellous bone but because the tabs possess the recited "configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within a vertebral body".

Although Marino states that the insert can be fabricated from donor bone graft material, this disclosure cannot be understood to apply to its anchoring fins which must possess at least one thin sharp edge capable of cutting into the vertebral endplates. Anchoring fins constructed of bone, even assuming that they could be shaped with a knife-like edge as shown in Marino, would undoubtedly lack the mechanical strength to effectively function in the manner described by Marino, i.e., to cut into the hard cortical bone characteristic of the vertebral endplates.

In view of the foregoing differences between applicants' claimed implant and the Marino implant, Claims 1, 2, 4, 5, 8, 9, 21 and 24 are believed to recite novel as well as nonobvious subject matter relative to the disclosure of this patent.

The Examiner has rejected Claims 1, 2, 4-7 and 9 under 35 U.S.C. § 103(a) as obvious over Godefroy et al. in view of Bianchi et al.

Godefroy et al. discloses an implant having a rigid open framework (for

accommodating a bone graft inserted therein prior to implantation) and is made from a metal or a rigid synthetic material. Like the Marino implant discussed above, the Godefroy et al. implant possesses annular external ribs that are intended to prevent both axial movement in translation and rotation of the implant by digging into the vertebral endplates (specification, column 2, lines 57-60 and column 4, lines 7-12). There is no disclosure or suggestion in Godefroy et al. of applicants' tabs which possess a "configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within a vertebral body". While Godefroy et al. recognizes the benefit of using bone material in the vertebral fusion process (for which Bianchi et al. is also cited) and provides spongy bone graft 100 (Figs. 3, 4 and 5) for this reason, the bone graft is nevertheless surrounded by a rigid structure. This arrangement has the disadvantage, *inter alia*, of stress shielding the vertebral fusion site at least to some extent, a drawback not encountered with an all-bone implant as claimed by applicants.

Bianchi et al, like Godefroy et al. with which it has been combined by the Examiner, lacks any suggestion of applicants' tabs which possess a "configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within a vertebral body". Such being the case, the combined disclosures of Godefroy et al. and Bianchi et al. still fail to describe a critical and patentably distinct feature of applicants' claimed implant.

For the foregoing reasons, Claims 1, 2, 4-7 and 9 herein are considered to define patentable invention over the combined teachings of Godefroy et al. and Bianchi et al.

The Examiner has rejected Claim 20 under 35 U.S.C. § 103(a) as obvious over Marino in view of Scarborough.

Marino, as previously noted, does not disclose applicants' tab elements. Although Scarborough discloses an implant fabricated from bone, e.g., human bone, like Marino it, too, fails to so much as hint at applicants' claimed tabs.

The Examiner has rejected Claim 22 under 35 U.S.C. § 103(a) as obvious over Marino in view of Lewandrowski et al.

Neither Marino nor Lewandrowski et al. disclose or suggest applicants' tab elements. Accordingly, Claim 22 is believed to define patentable invention over the combined Marino and Lewandrowski et al. disclosures.

The Examiner has rejected the method of installing an intervertebral implant of Claim 23 under 35 U.S.C. § 103(a) as obvious over Marino in view of Kuslich et al.

The method of Claim 23 recites the steps of "forming a stepped bore in a portion of two adjacent vertebrae, the stepped bore having a large diameter area and a reduced diameter area" and "rotating the implant to position the tabs within the enlarged diameter area of the bore".

Marino describes a method for installing its implant wherein the implant is rotated within the intervertebral space so that its knife-like anchoring fins will cut into the vertebral endplates and secure, or anchor, the implant in place. In contrast to this method, the method of applicants' Claim 23 requires the formation of a stepped bore in the vertebral endplates (a procedure which is described in Kuslich et al.) so that rotation of the implant within the intervertebral space will bring the tabs on the implant into alignment with, and seated within, the enlarged diameter area of the stepped bore thus locking the implant in place and inhibiting its axial or rotational displacement.

Neither Marino nor Kuslich et al. discloses the installation of an implant possessing

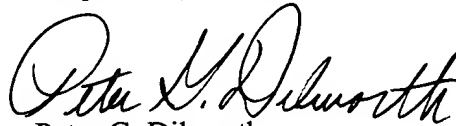
tabs intended to be seated within preformed recesses in the vertebral endplates. Therefore, it cannot be said to be obvious from Marino and Kuslich et al. to install an implant that neither of these individual references nor their combination discloses or suggests.

Under the circumstances, applicants' Claim 23 can only be regarded as patentable over Marino and Kuslich et al. no matter how their disclosures are considered or combined.

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Reconsideration and allowance by the Examiner of Claims 1, 2, 4-9 and 20-24 in light of the foregoing remarks are once again respectfully requested.

Respectfully submitted,



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